essential products, and young age groups, are included within the scope of the program.

To make perfectly clear the need for additional legislation, I would like to quote a significant passage from the FDA's January 2001 report, which stated the following:

A majority of marketed drugs are not labeled for use in pediatric patients, or are labeled for use only in specific pediatric age groups . . . And many of the drugs most widely used in pediatric patients carry disclaimers in their labeling stating that safety and effectiveness in pediatric patients have not been established. The absence of pediatric labeling information poses significant risks for children. Inadequate dosing information exposes pediatric patients to the risk of adverse reactions, usually age-specific adverse reactions that could be avoided if such information were provided in product labeling. The absence of pediatric testing and labeling may also expose pediatric patients to ineffective treatment through underdosing, or may deny pediatric patients therapeutic advances because physicians choose to prescribe existing, less effective medications in the face of insufficient pediatric information about a new medication.

These facts are very disturbing. Through our bill, we have sought to find a way to improve the labeling process. Since our law has not been implemented for very long, many labels are still in the process of being requested and negotiated by the FDA. In this new bill, the new timeframes established in the bill for labeling negotiations, together with the enforcement authority under the existing misbranding statute, will help to ensure that essential pediatric information generated from studies implemented under this law, will result in necessary and timely labeling changes.

Our bill establishes timeframes for responding to written requests, timeframes and processes for negotiating label changes, and authorizes the federal government to deem a drug misbranded if the company refuses to relabel its drug. The government would then begin an enforcement action under its existing authority to seek a court order regarding the relabeling of the drug.

Through the bill that we are about to pass today, we will ensure that priority drugs which lack patent or other market exclusivity will be tested for children. For example, the Ritalin label states the following:

Precautions: Long-term effects of Ritalin in children have not been well established. Warning: Ritalin should not be used in children under six years since safety and [effectiveness] in this age group has not been established.

The point is that Ritalin is being prescribed off-label for children under six years of age, and yet we do not know the safety and effectiveness, since it has only been tested in children older than six, and we do not know long-term effects on children of any age.

Our bill creates a mechanism to ''capture'' the off-patent drugs for which the Secretary determines additional studies are needed to assess the safety and effectiveness of the drug's use in the pediatric population.

In other words, our bill provides for the testing of some cases of these off-patent drugs.

By expanding the mission of the existing NIH Foundation to include collecting and awarding grants for conducting certain pediatric studies, we have provided a funding mechanism for ensuring studies that are completed for both off-patent drugs and those marketed on-patent drugs that a company declines to study—and for which the Secretary determines there is a continuing need for information relating to the use of the drug in the pediatric population.

That is the language in the bill. That is the correct area.

By first seeking funding through the Foundation, we provide a mechanism for drug companies to contribute to the funding of mainly off-patent drugs and also to a narrow group of on-patent drugs, including those for neonates, for which companies have declined to accept the written request to pursue the six month market exclusivity extension.

The Neonates, of course, are young children up to one-month of age.

If the Foundation lacks the funds to study that prioritized drug, the Secretary may then issue a request for proposal—''RFP''—for a third party to study the commercially available drug using money from a Research Fund that we create in this bill. The Secretary may then publish the name of the company that declined to study the drug, the name of the drug, and the indication or use that is being requested to be studied. This would ensure that more data is collected and reported, so that we can better understand which drugs are not being studied.

A condition of the RFP or contract with a third party is that all data and information generated from the pediatric study in the form of a report must be submitted to the NIH and the FDA. The FDA must then review the report and data and negotiate whatever labeling changes the FDA determines is appropriate.

I thank Senator BOND for his determined focus on helping to further ensure that neonates also benefit from this pediatric testing law. I congratulate and thank him. We have included neonates in the definition of ''pediatric studies'' to which this pediatric exclusivity applies. Throughout the bill we have also encouraged the inclusion of neonates in written requests, when appropriate.

To further ensure that the safety of children in clinical trials is protected, this bill requires that the Institute of Medicine—IOM—conduct a review of federal regulations, reports, and research involving children and provide recommendations on best practices relating to research involving children. The IOM is to consider the results of the study by HHS that Senator DODD and I included as part of the Children's Health act last year. I look forward to working with Senators DODD, FRIST, and KENNEDY on the issue of human subject protections, especially in focusing on protections of children participating in clinical trials.

I want to thank my friend, Senator DODD for his relentless efforts in making this reauthorization a reality, and for his relentlessness in improving the bill. I look forward to working on many more pediatric initiatives with him in the future.

Let me also thank Senators KENNEDY and CLINTON for their strong support of this bill and of children's health overall. Let me also thank Senator COLLINS for her support and for her work in regard to this bill.

I want to acknowledge and thank Debra Barrett, Jeanne Ireland, Christie Onoda, David Dorsey, David Nexon, Paul Kim, Christina Ho, John Gilman, and Tim Trushel for their hard work in helping us reach agreement on such a well-crafted bill. I cannot think of a bill that took more hard work, more Members and staff than this bill.

I also extend my appreciation to Elaine Holland Vining with the American Academy of Pediatrics for the tenacious effort, technical assistance, and expertise she brought to this bill. She is expecting her first child shortly, and I wish her and her husband, Paul, my very best wishes as they begin their family.

I also appreciate the diligent work of Mark Isaac and Natasha Bilimoria with the Elizabeth Glaser Pediatric AIDS Foundation in helping us negotiate and pass this important reauthorization.

Finally, I must say a very special thanks to a former member of my staff, Helen Rhee, who is now working for Senator FRIST on the HELP Committee. She has been absolutely instrumental in seeing this legislation through from its inception to its passage. Without her tireless efforts, her dogged determination, and a work ethic that is just unsurpassed, we would not be at this point today, we would not have seen this bill pass. Literally, right up until the last moment, literally, before the bill passed, Helen was continuing her work. So I pay tribute to her. This bill is a real tribute to her dedication and to her efforts.

So I thank Helen and all the members of the different staffs who have worked so hard on this bill.

Let me also take a moment to thank Senator HATCH and his staff, Bruce Artim, for their work in drafting language to correct and clarify this bill, specifically to clarify that pediatric exclusivity law is not and was never intended to eliminate incentives granted to generic drug manufacturers that are awarded 180 days of exclusivity under the 1984 Hatch-Waxman law for successfully challenging a patent.

Mr. President, I yield the floor.

The PRESIDING OFFICER (Mr. DAYTON). The Senator from Vermont.